

EF015 European Form

Field Safety Notice

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URGENT FIELD SAFETY NOTICE

Mobile Shower and Toilet Commode Aquatec® Ocean VIP Potential Risk of Tilting to the Front

Date: 23.04.2014 Ref: 40519

Important Safety Information:

In the interests of the safety of our customers we would like to bring to your attention that the Mobile Shower and Toilet Commode Aquatec® Ocean VIP can tilt to the front, when the casters are positioned backwards and the patient is laying his body weight to the front and/or is standing on the foot plate.

Reviewing our regular market observation we noticed that in rare cases the product tilted to the front, this despite the fulfillment of the stability requirements according the test requirements of EN 12182. As preventive action the instructions for use were updated in April 2010, a relevant warning label was placed on all caster side parts since June 2011 and additionally the instructions were updated beginning of April 2013.

We would like to make you aware about the possibility of mounting a front anti-tipping device (see picture) to prevent the shower commode of tipping forward. The option (article 1535936) can be ordered for all Aquatec® Ocean VIP, Ocean VIP XL and Ocean Dual VIP Mobile Shower and Toilet Commodes. This information is valid for all products manufactured between May 2006 (SN 13557203) and March 2013 (SN 14556654). Starting from April 2013 relevant information is included in the instructions for use which is attached to the product.



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Please be advised that if you have purchased products from within the affected serial number ranges you will be notified by Invacare in a separate information.

You need to make sure that the information in this notice is made available to all relevant personnel within your organisation and / or customer base.

Invacare acknowledges that this may be an inconvenience, but the information is essential for the safety of your patients and users.

If you have questions relating to this bulletin, or should require additional information, please contact your Invacare country representative, see www. Invacare.com ->Invacare Worldwide

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